UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

FEDERAL TRADE COMMISSION,

STATE OF ILLINOIS, and

STATE OF MINNESOTA,

Plaintiffs,

v.

Case No. 1:25-cv-02391

Hon. Jeffrey I. Cummings

GTCR, LLC,

GTCR BC HOLDINGS, LLC, and

SURMODICS, INC.,

Defendants.

<u>DEFENDANTS' OPPOSITION TO</u> <u>PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION</u>

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INTRODUCTION

BC Holdings' acquisition of Surmodics, if consummated, would create a new company with broader capabilities to better serve customers through a sophisticated biomaterials business (the "Merged Firm"). Plaintiffs Federal Trade Commission ("FTC") and the States of Illinois and Minnesota sued to enjoin the transaction, arguing that because Biocoat and Surmodics compete in certain overlapping business lines, the transaction would substantially lessen market competition. That is incorrect and reflects a fundamental misunderstanding of how competition in this industry works.

Nonetheless, to eliminate the need for a costly hearing, BC Holdings executed an agreement to sell substantial portions of Biocoat's coatings business to a strong buyer that is ready to compete immediately. This "Divestiture" includes the sale to of: (1) the entire Biocoat UV-cured coatings business; (2) Biocoat's currently-marked thermal-cured hydrophilic coatings ("Competitive Thermal Coatings"); (3) a Biocoat facility in Horsham, Pennsylvania; (4) the Biocoat® brand; (5) the HYDAK® brand, which Biocoat uses to market thermal and UV coatings; (6) manufacturing equipment; (7) eleven employees across a range of functions; and (8) two other "legacy" thermal-cured coating formulations that To avoid disruption to customers, the Divestiture does not include other legacy thermal-cured formulations, which Biocoat uses to service FDA-approved medical devices based on those specific legacy coatings, and which Biocoat does not use to compete for new customers.

In addition to the Divestiture, has agreed to license rights to the Competitive Thermal Coatings back to the Merged Firm to allow it to continue to innovate and develop thermal cured coatings, under a new brand name and in competition with To be clear, the Merged Firm will not own these coatings, but merely have a non-exclusive license from Ex. 14 at

-727-729 (Asset Purchase Agreement, July 29, 2025); Ex. 10 (Surmodics/ Biocoat Divestiture Term Sheet, May 28, 2025).

So the case before the Court today is not the one Plaintiffs initially filed. The Divestiture resolves Plaintiffs' alleged concern that the transaction will cause anticompetitive harm in the alleged market for "outsourced hydrophilic coatings." Defendants believe that the Divestiture resolves the dispute and there is no need to further burden the Court's time and resources. But if Plaintiffs persist in their dispute, Defendants will prove that the Court should allow the transaction as modified (the "Modified Transaction") to close.

For starters, Plaintiffs' understanding of the relevant market is fundamentally flawed. Plaintiffs base their case on the fallacy that there is a market comprised of "outsourced hydrophilic coating" technologies for medical devices, one that (1) includes two very different technologies (UV-cured and thermal-cured), while (2) excluding other technologies and methods for achieving lubricity (slipperiness). Plaintiffs' one-size-fits-all market does not account for the commercial realities of how competition works in the industry.

Plaintiffs' market definition purports to describe the options that medical device manufacturers ("OEMs" or "customers") have when choosing a coating for a catheter, guidewire, or other medical device that requires a lubricious coating. The definition is too broad because (1) OEMs that purchase coatings from Biocoat, Surmodics, and other coating suppliers generally invest in either thermal-cure or UV-cure equipment, so they cannot apply the other type without significant additional investment; (2) due to their physical or other properties, certain devices cannot use one coating type or the other (e.g., UV light cannot reach the inner diameter of a catheter), which even Plaintiffs concede accounts for at least of devices; and (3) even where both types might be options to test on the same device, OEMs typically rule one out due to

performance during the testing stage. At the same time, Plaintiffs' definition is too narrow because an OEM often can use another technology (e.g., hydrophobic), its own coating, or no coating at all. The method an OEM chooses to achieve lubricity depends on the OEM, the device, its design characteristics, the medical specialty for which the device will be used (e.g., neurovascular, cardiovascular), and, most importantly, whether a particular coating works for its intended purpose on the device (determined through feasibility testing). The failure to account for customers' many choices, and the reasons customers choose one technology over another defeats Plaintiffs' market definition.

Based on their incorrect market definition, Plaintiffs put forward market shares supposedly showing the transaction (without the Divestiture) is anticompetitive. But Plaintiffs' alleged market shares are divorced from today's competitive realities, as they are based primarily on *legacy revenue*—from long-term sales secured years and, in some cases, more than a decade ago. That legacy revenue is irrelevant as a matter of law to the question of what competition in the industry looks like today and, more importantly, what it will look like once the Modified Transaction occurs. *United States v. General Dynamics Corp.*, 415 U.S. 486, 501 (1974) (finding services "delivered under long-term requirements contracts ... do not represent the exercise of competitive power, but rather the obligation to fulfill previously negotiated contracts at a previously fixed price"). Thus, a better predictor for competitive significance, which Defendants employ, is the number of *recent FDA-approved device opportunities* that coating suppliers win.

After fourteen months of investigation and litigation, Plaintiffs have not shown that the transaction will likely result in anticompetitive effects, even without the Divestiture. Plaintiffs have not identified even *one* customer that has testified that the Merged Firm will charge higher prices, reduce quality, or stop innovating. Nor have Plaintiffs established that Defendants expect

that the transaction would allow them to raise price or stall innovation. The opposite is true: Defendants' reason for combining is to expand and improve products and services for customers.

The reality is that the Divestiture will make the marketplace more, not less, competitive than it is today. BC Holdings will sell the *entire* Biocoat UV business and Biocoat Competitive Thermal Coatings business to a multinational public company with revenues over eight times larger than Biocoat and Surmodics combined. has vast experience in medical device manufacturing , and the Divesture will convert it into a full-fledged and well-funded competitor to the Merged Firm. entry is not Defendants' speculation, it is the market reality. Plaintiffs complain about Defendants' timing for proposing the Divestiture, but they do not object to the outcome. The Divestiture fully addresses Plaintiffs' concern that the original transaction would have substantially reduced competition. Plaintiffs cannot carry their evidentiary burden, and the Court should deny Plaintiffs' motion for a preliminary injunction.

STATEMENT OF FACTS

On May 29, 2024, BC Holdings, which owns Biocoat, agreed to combine Biocoat's business with Surmodics' complementary business to form the Merged Firm. Ex. 21. BC Holdings' vision is to bring a broader range of differentiated coatings to OEMs, while establishing a more sophisticated biomaterials platform with breadth and scale to better serve OEMs through broader product selection and increased innovation. To resolve this case and provide certainty to customers and investors, BC Holdings agreed to the Divestiture to create a new competitor in The Modified Transaction creates two companies with offerings in *both* UV and thermal coatings, creating new competition and serving *procompetitive* goals.

¹ Exhibit numbers refer to the exhibits attached to the Sullivan Declaration.

A. The Lubricious Coatings Industry And The Parties

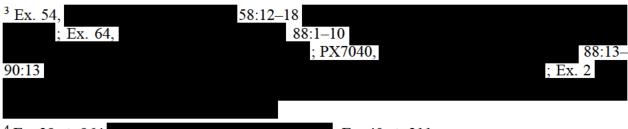
1. Many Suppliers Offer Diverse Lubricious Coatings And Additive Options

OEMs use lubricious coatings and additives on medical devices (like catheters and guidewires) to help physicians navigate tortuous pathways in the body while minimizing trauma to the patient. OEMs can add lubricity in numerous ways: (1) hydrophilic (water-loving) coatings, including Defendants' UV-cured and thermal-cured coatings; (2) hydrophobic (water-repelling) coatings, including PTFE (Teflon), parylene, and silicone oil; and (3) lubricious additives (*e.g.*, ProPell and Moibilize) incorporated into the underlying composite material of the medical device. PX7024,²

186:17–20, 232:3–6, 249:8–14, 250:16–251:6. These different technologies all serve the same purpose: lubricating the device. Some OEMs opt not to use lubricious coatings or additives at all given the device material, shape, and use.³ And others manufacture their own coatings in-house.

In addition to Biocoat and Surmodics, other companies that supply hydrophilic coatings include Harland Medical Systems, DSM Biomedical, Hydromer, Innovative Surface Technologies ("ISurTec"), Argon, Coatings2Go, Noanix, AST Products, LVD Biotech, BioInteractions, Jiangsu Biosurf, and jMedtech.⁴ Hydrophobic coating suppliers include Surface Solutions Group, Specialty Coating Systems, Roth Greaves, Zeus, Junkosha, Precision Coating, and VSi Parylene

² "PX" refers to exhibits submitted with Plaintiffs' preliminary injunction motion (Dkt. 173) ("Pl. Mem.").



⁴ Ex. 39 at -964 ; Ex. 40 at -311.

.⁵ OEMs that have developed their own in-house coating options include

2. Coatings Are Differentiated By Chemistry, Technology, And Capabilities

Biocoat and Surmodics (along with many other coating suppliers) sell hydrophilic coatings, but the chemistry that underlies their coatings and the way they are cured to adhere to the medical device's surface differ. So customers rarely choose between Defendants' coatings for the same device. Surmodics exclusively sells UV coatings. Biocoat historically sold thermal coatings, though it developed a UV coating in 2020 to reach demand not suited to thermal curing.

Thermal curing involves exposing a coating to heat for an extended period (30-60 minutes) to set the coating. Thermal curing usually involves "batch" curing, where the manufacturer moves the components to an oven for the curing's duration and then brings them back for any further assembly, finishing, or packaging. Because thermal curing does not require visibility to the device's surface, it is particularly suitable for coating the inner-diameters of medical devices and guidewires.

Water so PX7024, 233:11–23. Like thermal

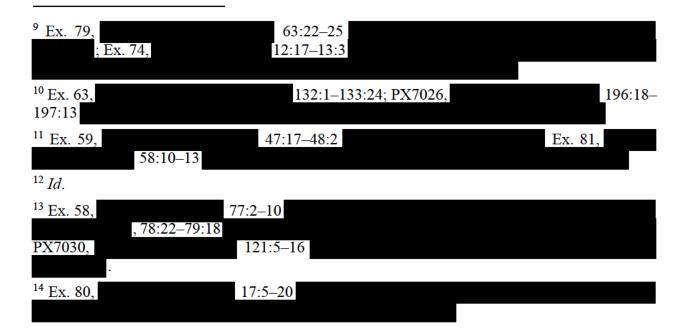
⁵ Ex. 62, 63:17–24, 88:6–14; Ex. 25 at -153; Ex. 26 at -491. ⁶ Ex. 65, 100:5-21, 113:2-115:16; PX7040, 11:11–24; Ex. 57, 76:18–23; $PX702\overline{5}$, 31:2-32:10; Ex. 15 at -650-51. ⁷ Ex. 56, Ex. 45 at -165. ⁸ Ex. 80, 25:1–20; Ex. 22 at -525; Ex. 72, 53:1-24 PX7041, 62:24–63:14 72:2-

coatings, medical device inner-diameters are a common application for hydrophobic coatings or liners.⁹ They are also used on guidewires.¹⁰

UV curing involves exposing a coating to direct UV light for only seconds to a few minutes to set the coating.¹¹ This speed makes UV curing suitable for high-volume applications.¹² UV curing cannot be used for the inner-diameter of a catheter; conversely, it is often the only option for heat-sensitive substrates and balloons.¹³

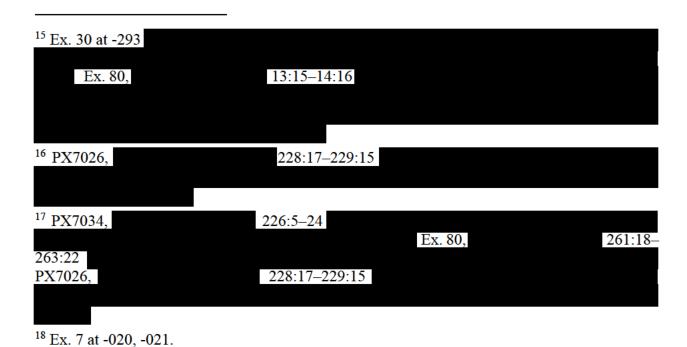
3. Different Coating Chemistries Work On Different Medical Devices

UV and thermal coatings rarely are viable options for the same device because: (1) OEMs generally invest in either thermal-cure or UV-cure equipment, so they cannot apply the other type without significant additional investment;¹⁴ (2) certain devices cannot use one coating type or the other (e.g., UV light cannot reach the inner diameter of a catheter), which Plaintiffs concede accounts for at least of devices, Pl. Mem. 5, 13–14; and (3) even where both might be conceivable options at the outset of device development, OEMs typically rule one out due to performance at the testing stage. Indeed, because UV and thermal typically do not satisfy



performance requirements on the same devices, several suppliers decided to develop both to address customer demand. As noted, Biocoat developed UV capabilities to add to its thermal offerings, while

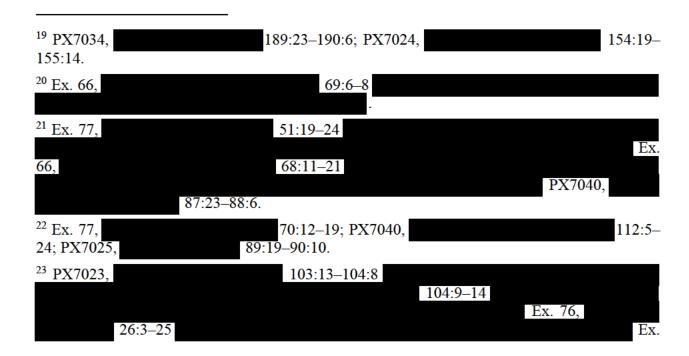
Likewise, a medical device's characteristics and functionality dictate whether hydrophobic is preferred to hydrophilic. ¹⁶ For example, hydrophobic coatings are generally more durable, so hydrophobic is often preferred for metal guidewires where durability can be more important than lubricity. ¹⁷ Customers also balance the wet lubricity advantages of hydrophilic coatings against the consistency of hydrophobic coatings and a customer may choose hydrophobic over hydrophilic when concerned about the latter



4. The Extensive Testing Required To Identify A Suitable Coating Makes Switching On Commercialized Devices Commercially Infeasible

Because a customer will not select a coating unless it works on a particular device, OEMs test coatings before choosing and submitting them for FDA approval.¹⁹ Only coatings that are tested and proven to meet performance requirements are real options for an OEM.²⁰ If a coating doesn't meet performance requirements, no discount will persuade the OEM to use that coating.²¹ Consequently, OEMs generally do not negotiate over commercial pricing unless a coating passes feasibility testing, at which point, as a practical matter, the OEM has already selected the supplier.²²

Additionally, a coating selected for a device typically remains on that device for its lifetime. That is because OEMs engage in extensive testing and complete a rigorous process to obtain FDA approval before commercializing a device. It would not make sense to change coatings only to repeat the process (and risk non-approval) after a device has been commercialized.²³ Coating suppliers therefore rarely attempt to persuade OEMs to switch coatings

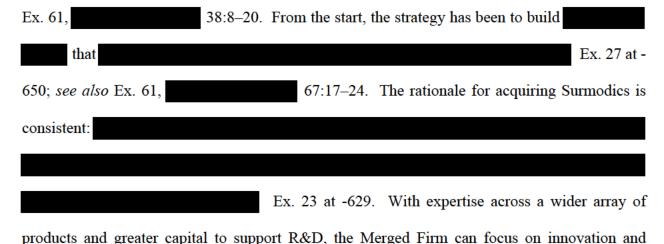


on commercialized devices.²⁴ For this reason, of Biocoat's and of Surmodics' 2024 revenue came from contracts signed with OEMs more than years prior. Ex. 47, Wong Rep. ¶ 470; *id.* at Exhibits A.III.6C-A.III.6D. The revenue for coating those devices is not contestable today.

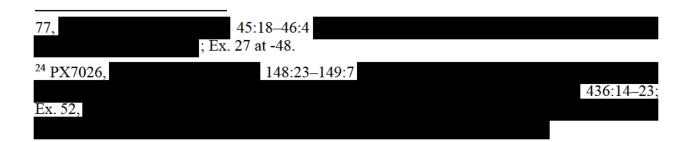
B. BC Holdings' Proposed Acquisition Of Surmodics

addressing more OEMs' lubricious coating and biomaterial needs.

BC Holdings originally invested in Biocoat to build a hub for innovation in biomaterials.



Additionally, as a larger, more sophisticated company, the combined business will have more diverse offerings, greater supply resiliency, and broader service and development capabilities to support OEMs. With locations in Pennsylvania and Minnesota, the Merged Firm will also be able to ship to customers from two locations instead of one, reducing freight costs and shipping



on shipping alone. *Id.* 337:17–23.

C. Divestiture To

To streamline the path to achieving these procompetitive benefits, on May 6, 2025, BC Holdings presented the Divestiture to the FTC staff. Conner Decl. ¶¶ 3–4. BC Holdings followed that initial presentation—which occurred nearly three months ago—with several subsequent presentations, written submissions, and an in-person formal meeting in hopes of addressing Plaintiffs' alleged concerns about the transaction. *Id.* ¶¶ 3–4, 12. As detailed below, the Divesture fully resolves the competitive issues Plaintiffs identify in their Complaint and pre-hearing brief.

LEGAL STANDARDS

"A preliminary injunction is an extraordinary equitable remedy that is never awarded as of right." *Starbucks Corp. v. McKinney*, 144 S. Ct. 1570, 1576 (2024). This is particularly so in the merger challenge context, where a preliminary injunction is "preliminary" in name only given that it "almost always obviates the need for further administrative proceedings" before the FTC. *In the Matter of Tempur Sealy Int'l, Inc.*, 2024 WL 4544179, at *1 (FTC, Oct. 15, 2024); *see also FTC v. Microsoft Corp.*, 681 F. Supp. 3d 1069, 1084–85 (N.D. Cal. 2023) ("the issuance of a preliminary injunction blocking an acquisition or merger may prevent the transaction from ever being consummated"). To secure a preliminary injunction, which effectively would kill the Modified Transaction, the FTC must make a "clear showing" that (1) it is likely to succeed on the merits and (2) the public interest and equities favor an injunction. *Starbucks*, 144 S. Ct. at 1575; 15 U.S.C. § 53(b) (removing irreparable-injury requirement for the FTC).

Section 7 of the Clayton Act prohibits mergers and acquisitions only where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. Plaintiffs must establish that the harm to competition is reasonably likely or probable,

not just possible. *See United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019); *United States v. Baker Hughes Inc.*, 908 F.2d 981, 991 (D.C. Cir. 1990) (Thomas, J.) ("[T]he ultimate issue" is "whether a transaction is likely to lessen competition substantially.").

Following the D.C. Circuit's decision in *Baker Hughes*, courts apply a burden-shifting framework to analyze the legality of a horizontal merger under Section 7. First, Plaintiffs must establish a *prima facie* case that the transaction (here, the Modified Transaction) "will substantially lessen competition" by showing that it "will lead to undue concentration in the market for a particular product in a particular geographic area." *Baker Hughes*, 908 F.2d at 982. If Plaintiffs fail to prove their *prima facie* case, their motion should be denied without further inquiry. Otherwise, the analysis proceeds to step two, where Defendants bear the burden to show with evidence that the "*prima facie* case inaccurately predicts the relevant transaction's probable effect on future competition." *Id.* at 982, 991. A "clear showing" is not required. *Id.* at 989. If Defendants satisfy their burden, the analysis proceeds to step three, where Plaintiffs bear the burden to "produc[e] additional evidence of anticompetitive effect" and "merges with the ultimate burden of persuasion, which remains with [Defendants] at all times." *Id.* at 983; *see* Fed. R. Evid. 301 (burden of persuasion does not shift from party that had it originally).

ARGUMENT

I. PLAINTIFFS CANNOT CARRY THEIR BURDEN BECAUSE THE DIVESTITURE INCREASES COMPETITION

To prevail, Plaintiffs have the burden to establish a *prima facie* case of likely substantial anticompetitive effects in a relevant market *and* carry the ultimate burden of persuasion. They cannot meet those burdens because the Divestiture fully resolves their competition concerns.

A. The Divestiture Creates A New, Stronger Competitor, Which Will Have Everything It Needs To Compete In *Both* UV And Thermal Coatings

To resolve Plaintiffs' concerns with the original transaction, BC Holdings signed a divestiture agreement that empowers to compete in both the UV- and thermal-cured coating businesses. In evaluating a divestiture, courts look to the scope of the assets divested and the buyer, both of which are more than sufficient to address Plaintiffs' concerns here.²⁵

As to the assets, at closing will acquire the assets needed to compete in UV- and thermal-cured coatings. As for the Divestiture buyer's qualifications, is one of the world's largest medical companies, with over substantially larger than Surmodics and Biocoat combined. As a medical device and putting it in the pole

²⁵ Plaintiffs have cited the possibility that other divestiture configurations may exist or have been considered. Dkt. 199 at 2 (seeking discovery on materials related to "fully divesting Biocoat as a standalone company"). However, under settled law, the only pertinent transaction here is the Modified Transaction and not other hypothetical alternatives. *Microsoft*, 681 F. Supp. 3d at 1093 (as part of its "*prima facie* burden," "the FTC must address the circumstances surrounding the merger as they actually exist"); *FTC v. Arch Coal, Inc.*, 2004 WL 7389952, *1 (D.D.C. July 7, 2004) (evaluating the divestiture sale as-is because ignoring it would require the Court to assess a "purely hypothetical transaction of the Commission's making—that none of the parties are proposing").

²⁶ Ex. 61, 196:12–22; Ex. 33 at 3; *id.* at 11. 183:9–184:4 Ex. 61,

position to compete for those opportunities.²⁸ The hydrophilic coating businesses through the Divestiture complement its

Put simply, the Divestiture addresses the alleged problematic overlap in the alleged "outsourced hydrophilic coatings" market, which is the sole basis for Plaintiffs' Section 7 claim.

Going forward, will (1) completely replace Biocoat as an independent competitor to the Merged Firm in UV coatings and (2) launch as a new competitor in thermal-cured coatings. supercharges Biocoat's current competitive footprint with the reach and resources of one of the world's largest medical device development companies. Additionally, with the Competitive Thermal Coatings licensed to the Merged Firm, the Divestiture increases the number of competitors with thermal and combined offerings, enhancing competition. The diagram below compares competition today with competition after closing (excluding other competitors in the industry for simplicity):

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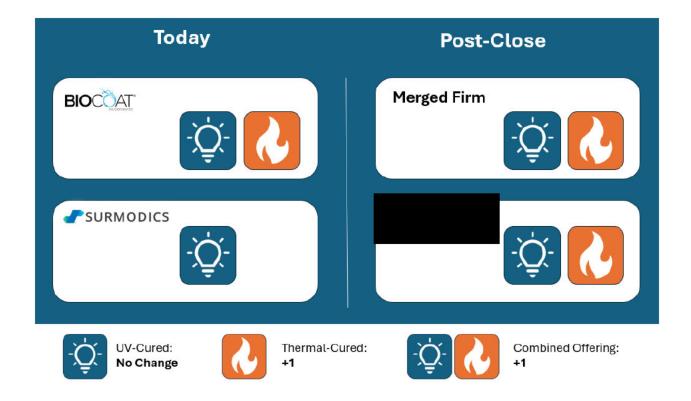
²⁸ Ex. 75,

269:5–270:2
; Ex. 34 at -760

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²⁹ Ex. 75,

170:6–171:2, 195:18–196:13



B. The Divestiture Is Sufficient To Alleviate Any Competitive Concerns With The Challenged Transaction

Courts evaluating a divestiture's effect on competition consider several factors, including (1) the likelihood of the divestiture, (2) the experience of the divestiture buyer, (3) the scope of the divestiture, (4) the independence of the buyer from the merging seller, and (5) the purchase price. *FTC v. Tempur Sealy Int'l, Inc.*, 768 F. Supp. 3d 787, 858 (S.D. Tex. 2025); *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 304 (D.D.C. 2020). Analyzing those factors confirms that Plaintiffs should approve the Modified Transaction by way of settlement and, if not, the Court should deny Plaintiffs' request for injunctive relief.

First, the divestiture is certain.³⁰ It is not contingent on anything other than the transaction closing. The buyer has been selected, the assets agreed to,³¹ and the purchase agreement signed.³²

Second, is a robust buyer uniquely well-positioned to compete immediately on Day 1.

Third, as to the scope of the divestiture, Biocoat is divesting all components needed to make a successful competitor in both the UV-cured and thermal-cured coatings businesses, as will receive everything it requested and everything it needs to compete.³³ While Biocoat will retain its older, legacy thermal coatings business lines, there is no current or future competition for these coatings. Some of the products that use these coatings have been on the market for decades and use the old coatings because the FDA approved them for that device. Ex. 61,

267:1–3

Those past sales are irrelevant to ability to compete for future opportunities—which is what Section 7 is concerned about.

Finally, the purchase price reflects an arms'-length agreement. BC Holdings selected after a multi-month process in which it

³⁰ Ex. 14 (Asset Purchase Agreement, July 29, 2025).

The list of divestiture assets, including Biocoat's Witmer Road facility, associated coating equipment, and eleven full-time personnel, reflects Biocoat's response to the FTC. Ex. 12 at -129 cf. Ex. 9. See also Conner Decl. ¶¶ 3–4, 12.

Prior to the asset purchase agreement's execution on July 29, 2025, the contours of the Divestiture were set and presented to the FTC on May 6, 2025 (Ex. 12), May 13, 2025 (Ex. 11), June 11, 2025 (Ex. 13), and separately by on June 10, 2025 (Ex. 34). See also Conner Decl. ¶¶ 3, 11.

³³ Ex. 61,

.34 Defendants did not select ; rather, they conducted a robust process and identified a company able to compete vigorously on day one.

Plaintiffs cite three cases rejecting a divestiture due to the sufficiency of the divestiture package or the strength of the buyer. Pl. Mem. 52. If anything, these cases confirm the sufficiency of Defendants' divestiture. In all three, the courts found that the scope of the divested assets, inexperience of the buyer, and ongoing dependence on the merged entity raised serious questions about the buyer's ability to compete effectively and independently. *FTC v. Kroger*, 2024 WL 5053016, at *26–30 (D. Or. Dec. 10, 2024) ("The deficiencies in the divestiture scope and structure create a risk that some or all of the divested stores will lose sales or close, as has happened in past C&S acquisitions."); *United States v. Aetna*, 240 F. Supp. 3d 1, 64–73 (D.D.C. 2017); *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 73–78 (D.D.C. 2015). By contrast, already has significant industry experience and deep customer ties and will receive all the assets it needs to compete without relying on Biocoat.³⁵

³⁴ Conner Decl. ¶¶ 5–7, 12.

Plaintiffs' fleeting suggestion that it is improper to consider the Divestiture during the preliminary injunction phase (Ex. 53, 7/25/2025 Tr. 36:6–12, 38:17–39:3, 40:24–41:2) is wrong as a matter of law. See United States v. UnitedHealth Grp. Inc., 630 F. Supp. 3d 118, 132–33 (D.D.C. 2022) (government must evaluate "the combined effect of the merger and the divestiture" in prima facie case); RAG-Stiftung, 436 F. Supp. 3d at 303–04 (considering divestiture in evaluating FTC's proposed relevant market); Microsoft, 681 F. Supp. 3d at 1093 (as part of its "prima facie burden," "the FTC must address the circumstances surrounding the merger as they actually exist"); Illumina, Inc. v. FTC, 88 F.4th 1036, 1058–59 (5th Cir. 2023) ("To rebut Complaint Counsel's prima facie case, Illumina was only required to show that the Open Offer sufficiently mitigated the merger's effect such that it was no longer likely to substantially lessen competition."); Tempur Sealy Int'l, 768 F. Supp. 3d at 858 (considering "remedial commitments" and divestiture "as rebuttal to the FTC's prima facie case").

C. Plaintiffs Have No Plausible Reason To Reject The Divestiture

Defendants shared the Divestiture with Plaintiffs in late April, and discussed it with Plaintiffs in detail in the following weeks.³⁶ Plaintiffs rejected the initial proposal, so Defendants offered a revised proposal on May 6, 2025 with additional features, including the transfer of Biocoat's Witmer facility and employees.³⁷ Since then, Defendants have provided all the information Plaintiffs have requested, including communications with bidders, the divestiture term sheet, letters of interest from multiple bidders, diligence correspondence, integration planning materials, and the signed Asset Purchase Agreement and related agreements (*e.g.*, the Transition Servies Agreement).³⁸ has also provided ample divestiture-related discovery.³⁹ Additionally, more than eighteen depositions have included questioning by Plaintiffs and Defendants on the Divestiture.⁴⁰

Throughout, Plaintiffs have remained silent on the sufficiency of Defendants' proposal. Dkt. 200 at 2. Plaintiffs' challenge, however, is that once the Court considers—as it must—the *actual* competitive dynamics that will *in fact* exist when the deal closes and Divestiture is complete, Plaintiffs cannot establish their *prima facie* case.⁴¹ Nor can they carry their burden of

³⁶ Conner Decl. ¶¶ 3–4, 12.

³⁷ *Id*.

 $^{^{38}}$ Id. ¶¶ 7–8, 12. BC Holdings has responded to seven requests for production, two requests for admission, and six interrogatories expressly related to the divestiture. Id. ¶¶ 6–7, 12.

 $^{^{39}}$ Id. \P 9. has produced more than . Id.

⁴⁰ *Id*. ¶ 10.

⁴¹ Because Defendants agreed to execute the Divestiture at closing (as opposed to agreeing to follow through only if the Court finds it liable first), the Court should evaluate the Modified Transaction's legality and whether Plaintiffs can carry their burden to establish a *prima facie* case by taking into account the Divestiture's effect. *See UnitedHealth*, 630 F. Supp. 3d at 133 ("the burden of proof regarding the acquisition—including the divestiture—remains on the Government at the *prima facie* stage"); *Tempur Sealy*, 768 F. Supp. 3d at 834 (the inquiry at the *prima facie* stage necessarily includes defendant's "remedial commitments undertaken to lessen any impact of

persuasion. The Court should accordingly deny the preliminary injunction. *See FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 114-15 (D.D.C. 2004) (denying preliminary injunction where transaction "d[id] not reduce the number of competitors").

II. PLAINTIFFS CANNOT CARRY THEIR BURDEN UNDER THE BAKER HUGHES BURDEN-SHIFTING FRAMEWORK

Plaintiffs cannot show that the Modified Transaction is likely to result in substantial anticompetitive effects. Moreover, although Section 7 does not require that the challenged transaction be affirmatively procompetitive, the Modified Transaction is: under the status quo, Biocoat (but not Surmodics) will provide thermal coatings; with the Modified Transaction, both the Merged Firm and will sell both UV and thermal coatings (*i.e.*, the number of thermal competitors increases and the number of competitors offering both thermal and UV increase). While the number of firms offering UV coatings will stay the same, the UV divestiture assets will go to which is much larger than either Surmodics or Biocoat.

Plaintiffs cannot carry their burden under the *Baker Hughes* burden-shifting framework for three reasons. First, Plaintiffs cannot establish a *prima facie* case because their market definition is incurably flawed. Second, even if Plaintiffs make their *prima facie* case, Defendants will show that, even without the Divestiture, Plaintiffs' market shares are not indicative of future harm and that, with the Divestiture, the shares are so misleading as to be irrelevant. Finally, Plaintiffs cannot carry their ultimate burden of showing that the transaction, with or without the Divestiture, will have anticompetitive effect; in fact, the record is strikingly silent on this dispositive issue.

competition—for example, divestiture of certain [assets]"); *RAG-Stiftung*, 436 F. Supp. 3d at 304 (evaluating divestiture in context of FTC's proposed relevant market in its *prima facie* case); *Microsoft*, 681 F. Supp. 3d at 1093 (as part of its "*prima facie* burden," "the FTC must address the circumstances surrounding the merger as they actually exist"); *see also United States v. AT&T*, *Inc.*, 310 F. Supp. 3d 161, 217 n.30, 241 n.51 (D.D.C. 2018) (government failed to meet its burden in part because it did not consider defendant's arbitration agreement that "will have real-world effects").

A. Plaintiffs Cannot Prove A *Prima Facie* Case Based On An Alleged "Outsourced Hydrophilic Coatings" Market

Plaintiffs cannot establish a *prima facie* case that the Modified Transaction will substantially lessen competition in their proposed "outsourced hydrophilic coatings" market. Plaintiffs' alleged market, the foundation of their entire case, does not reflect reality in the coating industry. As more than six decades of Supreme Court precedent makes clear, a Section 7 plaintiff must prove its antitrust market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 324 (1962) (identifying the relevant market is a necessary predicate to finding a Clayton Act violation). And Plaintiffs cannot make up for their fundamentally flawed market merely by showing the elimination of "head-to-head competition between close competitors." Pl. Mem. 32–33.

1. Plaintiffs' Alleged Market Is Inconsistent With "Commercial Realities" And Lacks Factual and Economic Support

Market definition is a "pragmatic, factual" exercise, not "a formal, legalistic one," and must be consistent with "the commercial realities of the industry." *Brown Shoe*, 370 U.S. at 336. The purpose of market definition is to determine, from the consumers' perspective, the "area of effective competition," *id.* at 324—what competes with the merging parties' products to meet customer needs. Plaintiffs' market must include *all options* based on "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Id.* at 325; *see also United States v. E.I. du Pont de Nemours*, 351 U.S. 377, 395 (1956); *Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1330 (7th Cir. 1981) ("the concept of economic substitution is the primary means by which to define a product market"). Plaintiffs' failure to prove their proposed antitrust market requires denial of their request for injunctive relief. *See FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1051 (8th Cir. 1999) (noting that finding a relevant market is "essential"); *Tempur Sealy*, 768 F. Supp. 3d at 815 (FTC's failure to prove a relevant market requires denial of injunctive relief); *Arch Coal*, 329 F. Supp. 2d at 116—

17 ("even Section 13(b) cases must be resolved on the basis of the record evidence relating to the market and its probable future").

Plaintiffs' "outsourced hydrophilic coating" market is inconsistent with "the commercial realities of the industry" because it disregards how competition occurs, what products customers view as substitutes given their product-specific needs, and how customers choose a coating supplier for a particular device. Three flaws in Plaintiffs' proposed market show why.

First, the proposed market is too broad, and therefore violates the bedrock antitrust law requirement to define the narrowest possible market. Market definition begins "by examining the most narrowly-defined product or group of products sold by the merging firms." Arch Coal, 329 F. Supp. 2d at 120 ("Relevant market analysis is based on the 'narrowest market' principle."). Ignoring this rule, Plaintiffs' market includes both thermal and UV coatings, even though many customers can use only one or the other for their specific medical device. In some cases, the customer already owns curing equipment for one technique (but not both) and will not consider the other type. In other cases, the customer excludes either UV or thermal coating based on the area being coated (e.g., inner diameters of catheters cannot be cured with UV light) or the type of substrate, additives, and processes used.⁴² Finally, even when customers can test both UV and thermal on a device, most often one or the other fails because of the complex, differentiated cure chemistries of the coatings.

In these scenarios, UV and thermal coatings are not reasonably interchangeable due to the physical or chemical characteristics of a given device. Indeed, this lack of interchangeability is



precisely why Biocoat developed a UV coating: doing so would grow Biocoat's sales without cannibalizing its thermal sales.⁴³

Plaintiffs concede that the two types of coatings are not substitutes for each other of the time. Pl. Mem. 13-14 (quoting Ex. 51, (Petra (DSM) Decl.) ¶ 5). Plaintiffs therefore acknowledge that in cases, a UV or thermal customer could not switch to the other. See United States v. Household Fin. Corp., 602 F.2d 1255, 1265 (7th Cir. 1979) (reversing finding that relevant market included services from both finance companies and other financial institutions); id. (market was too broad because evidence suggested "anywhere from 15 to 50 percent" of finance company customers could not use other institutions' services); RAG-Stiftung, 436 F. Supp. 3d at 287 ("oversimplification" in market definition ignored how "suppliers compete for customers served by [chemical's] countless end uses—accounting for products' variations in purity, concentration, stabilizer chemicals, profitability, and even regulatory approval").

Plaintiffs ask this Court to ignore all of this and define a market around products that are, in many cases, not substitutes for the very customers they claim the Modified Transaction harms. The Court should decline to do so. *See United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 193 (D.D.C. 2001) (rejecting "government's overly narrow and static definition of the product market" based on analysis of customers' needs).

Second, Plaintiffs' market is too narrow because if they are correct that it includes both UV and thermal coatings, then it should also include other coating substitutes, such as hydrophobic coatings, silicone lubricants, lubricious material additives, or no coating at all.⁴⁴ Plaintiffs ignore

⁴³ See PX7024,

202:6–17

; Ex. 47, Wong Rep. ¶ 219 and Exhibits 13A, 13C

⁴⁴ Ex. 63,

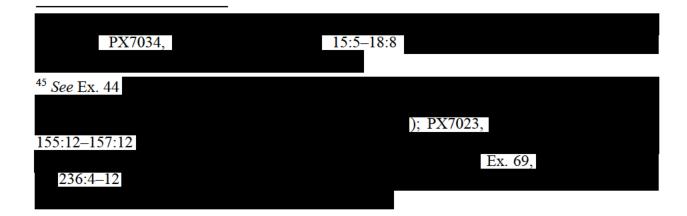
PX7026,

132:1–13

196:18–197:13

numerous examples of companies approaching Surmodics or Biocoat about a hydrophilic coating and ultimately choosing a non-hydrophilic option. The law does not allow Plaintiffs to assume away these commercial realities and treat all customers as having the same two alternatives for all devices, where other options exist. *See FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 87–89 (N.D. Ill. 1981) (rejecting FTC's narrow market of brominated flame retardants that did not account for "competition at the end use level" between flame retardants made of different chemicals); *Tempur Sealy*, 768 F. Supp. 3d at 815–25 (evaluating *Brown Shoe* factors and rejecting FTC's narrow market of "premium" mattresses defined by price point).

Third, by limiting the alleged market to "outsourced" hydrophilic coatings, Plaintiffs exclude coatings made by customers "in house," which are yet another option. Plaintiffs defend this limitation on the grounds that in-house coatings are not sold to other OEMs and that OEMs that use in-house coatings also buy outsourced coatings for certain devices. Pl. Mem. 14. But that is not how market definition works. The market must include all products that have "competitive significance in the relevant market." Sungard, 172 F. Supp. 2d at 186. The issue "is not whether the companies that currently use internal solutions have the capacity to enter the market as vendors for others, but whether the customers that currently use" outsourced coatings would switch to inhouse coatings. Id. at 187–88 (finding internal solutions part of relevant market because evidence



showed that customers switched to internal solutions and others threatened to do so). Defendants routinely compete with in-house coating options, at times losing sales to in-house coatings. *See* Ex. 78, 82:15-84:1; Ex. 42.

a. The *Brown Shoe* Factors Do Not Support Plaintiffs' Flawed Market Definition

Plaintiffs defend their market by relying heavily on the *Brown Shoe* "practical indicia" factors Pl. Mem. 13–26. They cite largely the same body of evidence to support each factor: declarations drafted and/or edited by the FTC, and testimony from FTC investigational hearings (where Defendants were not present) that discovery under the Federal Rules did not confirm. Plaintiffs tellingly do not cite evidence of contemporaneous customer decision-making that supports their alleged market. *See RAG-Stiftung*, 436 F. Supp. 3d at 321 ("declarations are not enough to outweigh the overall trends ... reflected in the record"). Indeed, for each declaration or investigational hearing transcript Plaintiffs cite, there are more examples inconsistent with Plaintiffs' market. Applying the practical indicia factors demonstrates that Plaintiffs' proposed market definition fails under *Brown Shoe*. 46

Practical indicia demonstrate that UV- and thermal-cured coatings are not reasonably interchangeable for many customers and devices. The evidence demonstrates that UV and thermal are not substitutes because they address peculiar characteristics and uses, as each device

⁴⁶ Plaintiffs' treatment of the *Brown Shoe* factors reflects the extensive differences among customers and devices. Pl. Mem. 23 (coatings providers work with customers to "optimize the coating to meet the needs of a particular device"); *id.* 26 ("coatings' different properties suit different purposes"). For instance, Plaintiffs discuss at length the uniqueness of neurovascular customers, yet their proposed market treats neurovascular customers as having the exact same consideration set as cardiovascular and peripheral vascular customers. *Id.* 26.

has unique performance specifications.⁴⁷ The parties' documents underscore this point.⁴⁸ There is **industry and public recognition** of different markets evidenced by the fact that industry players refer to UV and thermal coatings as distinct types.⁴⁹ Plaintiffs point to documents that discuss references to "hydrophilic coatings," but generalizations do not prove competition. *Cf.* PX7032,

"Without a showing of the role that industry and public perception ... play in motivating and shaping consumer decisions, the demarcation of a submarket ... cannot be justified." *Thurman Indus., Inc. v. Pay 'N Pak Stores, Inc.*, 875 F.2d 1369, 1376 (9th Cir. 1989). Thermal and UV coatings also have **different production methods** because they are applied differently. Thermal is cured with heat, while UV

FX7024,

191:21–192:3

Ex. 59,

(Fx. 72,

(Fx. 57,

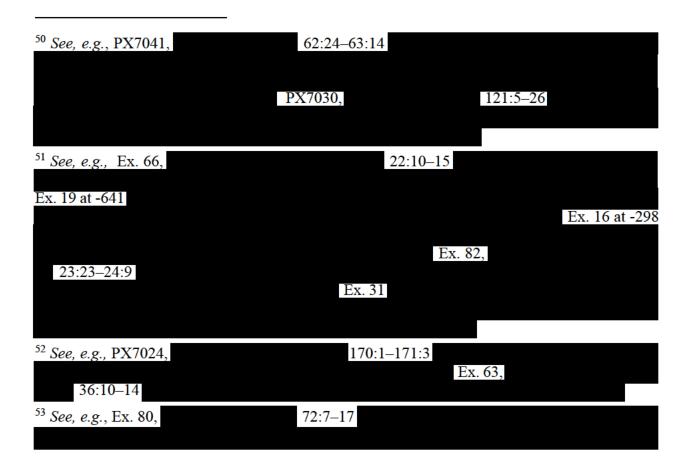
(Fx.

48 Ex. 8 at -904 ; Ex. 22 at -525 -527 ; Ex. 24 at -109

⁴⁹ See e.g., Ex. 49, HYDROMER, UV Coating vs Thermal Coating Review: Which one should you choose? (showing chart identifying different processes, speeds, batch sizes, energy consumption, durability, consistency, suitability for complex shapes, heat sensitivities, finishes, and eco-friendliness between UV and thermal coatings), available at https://hydromer.com/uv-coating-vs-thermal-coating.

is cured with light. This is an important difference for many products where heat or light curing is not feasible.⁵⁰ Different production methods mean **the production facilities**, **processes**, **and equipment required for UV- and thermal-curing are also different**. A customer may decide to use a specific curing method because it already has the equipment necessary to use that method, and switching to an alternative method is resource and time consuming.⁵¹

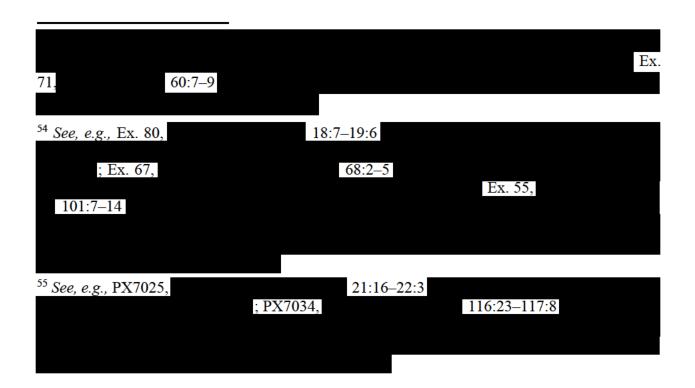
UV and thermal coatings also have **distinct customers** because the customers have distinct technical specifications for each device.⁵² UV and thermal likewise have **distinct prices and pricing models**. The evidence shows that each coating may be sold in various ways (*e.g.*, including powders and premix solutions), in various units (*e.g.*, by the gram, liter, or device), and through different pricing models (*e.g.*, by product amount, device amount, or through royalties). There are more pricing differences than similarities within and among thermal and UV coatings.⁵³



Finally, there is no question that UV and thermal have **specialized vendors**. Within Plaintiffs' proposed outsourced coatings market, there are firms that focus on thermal curing (*e.g.*, Biocoat) and firms that focus on UV curing (*e.g.*, Surmodics).⁵⁴

Practical indicia demonstrate that other methods of achieving lubricity are reasonably interchangeable for many customers and devices. Plaintiffs seek to include UV and thermal coatings in the market but exclude other substitutes that are just as interchangeable. Those substitutes include hydrophobic coatings, silicone lubricants, lubricious material additives, or no coating at all. This broader array of non-hydrophilic lubricious coatings belong in any market that includes both UV and thermal, as the Brown Shoe factors illustrate.

Plaintiffs argue that UV and thermal are reasonably interchangeable because they address similar characteristics and uses, but they do not account for other methods of achieving lubricity that address the same **peculiar characteristics and uses.**⁵⁵ For example, hydrophobic coatings (e.g., PTFE, silicon oil) are reasonably interchangeable with hydrophilic coatings for achieving



the desired performance level depending on the device.⁵⁶ Even no coating can achieve the same characteristics and uses depending on the use case.⁵⁷

Plaintiffs focus on documents that refer to "hydrophilic coatings" and/or a hydrophilic coatings "market," while disregarding documents that take a broader view and reflect industry and public recognition that there are alternative methods to achieve lubricity. For example, Plaintiffs cite a slide from a Biocoat Board presentation titled,

Pl. Mem. 19 (citing PX1171 at -009), but they do not address the preceding slide titled

That slide shows

Other documents reflect the same view. See, e.g., Ex. 35 (summarizing). Courts require a more consistent view of the contours of the market to find this practical indicium satisfied. See, e.g., United States v. Anthem Inc., 236 F. Supp. 3d 171, 196 (D.D.C. 2017); Sysco Corp., 113 F. Supp. 3d at 30.

As noted above, UV and thermal coatings each have **unique production methods.** To the extent Plaintiffs claim thermal and UV are similarly situated, however, non-hydrophilic coatings are no different. Coatings can be applied by dipping the device in the coating or spraying the

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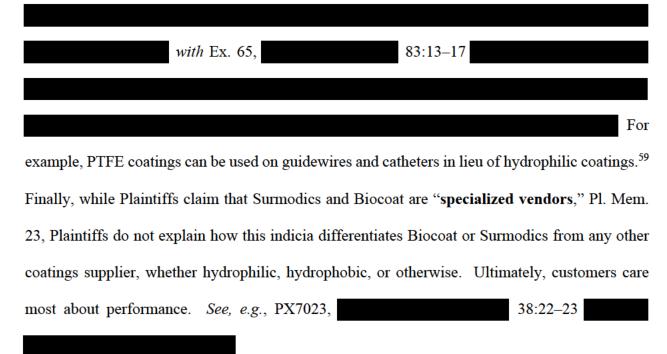
⁵⁶ See, e.g., PX7024,

233:11–20
, 244:11–18

246:2–8

device with the coating. The coated device is evaluated for the coating's visual uniformity, adherence, durability, and lubricity.⁵⁸

Ultimately, the choice of a coating is highly customer and device specific. Plaintiffs generalize and suggest that there are **distinct customers** in the market for "outsourced hydrophilic coatings." Yet among customers choosing hydrophilic coatings, there are a number simultaneously considering other methods of achieving lubricity. *Compare* Pl. Mem. 17 (claiming



Practical indicia demonstrate that in-house coatings are reasonably interchangeable for many customers and devices. As with non-hydrophilic options, Plaintiffs seek to exclude in-house

29

⁵⁸ Compare Ex. 74,

30:10–13

to Ex.

32

see also Ex. 5 at -002

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59 See, e.g., PX7034,

; Ex. 54,

73:23–74:3, 79:1-6

30:10–13

to Ex.

30:10–13

124:23–125:1

32:13–16, 33:4–7, 60:24–61:11,

coatings because they are *sometimes* not a substitute for certain customers and certain devices. But for customers who can and do turn to in-house as an option, the option belongs in the market, as the *Brown Shoe* factors confirm.

With regard to **peculiar characteristics and uses**, many customers and suppliers consider in-house coatings are an alternative to third-party suppliers given the similar characteristics and uses. When it comes to **industry and public recognition**, industry players and commentators recognize the competitive pressure that comes from in-house coatings. In-house coatings also cannot be distinguished on the basis of having **unique production facilities**. There is nothing technologically unique about in-house hydrophilic coatings that distinguishes them from outsourced hydrophilic coatings. Of course, there are certain customers of hydrophilic coatings that do not have in-house coatings. Defendants do not contest that. But for those who do have in-house options, such as

60 See, e.g., Ex. 67,

81:21–84:8

Ex. 82,

34:19–35:10

PX7025,

at 57:2–18

73:19–74:6

; Ex. 3
; Ex. 1

Ex. 69,

236:4–12

61 See, e.g., Ex. 4 at -844

Ex. 20 at

62 See, e.g., Ex. 70,

Ex. 37

among customers for purpose of assessing reasonable interchangeability. See FTC v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 48 (D.D.C. 1998) (finding "different classes of customers have varied ability to substitute the services currently provided by wholesalers" and large customers able to "replace the services of a wholesaler with an internally-created delivery system ... should be included in the same market"); Sungard, 172 F. Supp. 2d at 187 ("what is significant" for market definition is "whether the customers that currently use [outsourced product] would switch to an internal [product] in response to a" price increase). Finally, while Plaintiffs do not engage with the evidence, customers who have or could develop an in-house coating use the alternative to obtain more favorable terms reflecting sensitivity to changes in price, quality, and terms.⁶³

The *Brown Shoe* factors confirm that customers' needs and circumstances are too varied to all fit into Plaintiffs' "outsourced hydrophilic coatings" market. *Sungard*, 172 F. Supp. 2d at 189 ("At best, this conflicting evidence defies categorization, but only highlights the difficulty in this case—any generalizations regarding customer behavior cannot be arrived at with any certainty, since it depends on a host of factors, including the ... particular circumstances and needs of the customer."); *see Tempur Sealy*, 768 F. Supp. 3d at 822–23 (evaluating *Brown Shoe* indicia and finding customer behavior did not support proposed product market distinguishing "premium" mattresses from less expensive mattresses).

63 See, e.g., PX7040,

Ex. 83,

Ex. 37

b. The Incurable Flaws In Dr. Fix's Hypothetical Monopolist Test Cannot Save Plaintiffs' Market Definition

Plaintiffs claim that Dr. Fix's application of the hypothetical monopolist test ("HMT") supports their market definition. Pl. Mem. 27–28. The HMT is a test used to analyze whether a group of products is too narrow to be a relevant antitrust market. The HMT asks whether a hypothetical monopolist that controls that group of products could profitably raise prices by a small amount, or if too many customers would switch to other products that the lost sales would make the price increase unprofitable. If the price increase would be profitable, the group of products "passes" the HMT and can be considered a relevant market.

Dr. Fix describes this test, but then fails to run it. Ex. 47, Wong Rep. ¶¶ 277–80 (citing Fix Rep. ¶¶ 97–98). Rather than evaluate how many customers would switch to other products in response to the price increase, Dr. Fix assumes that the percentage is based on Ex. 46, Fix Rep. ¶ 97. Based on this assumption, he concludes that the FTC's proposed market passes the HMT. Ex. 47, Wong Rep. ¶ 278 (citing Fix Rep. ¶¶ 97–98). But Dr. Fix's conclusion is a function of his assumption, not empirical analysis. Ex. 47, Wong Rep. at ¶¶ 278, 280.

The HMT must start with "the most narrowly-defined product or group of products" and only expand to add more products if the price increase would not be profitable." *Arch Coal*, 329 F. Supp. 2d at 120. HMT cannot reveal a product market to be too broad, only too narrow. *RAG-Stiftung*, 436 F. Supp. 3d at 299 n.11. Therefore failure to start with the narrowest set of products makes the results unreliable. Dr. Fix makes this error by starting with a hydrophilic coatings market instead of a narrower one (*e.g.*, UV-only or thermal-only). In fact, using the percentage of customer substitution implied by other portions of Dr. Fix's report, his HMT would prove that UV coating are a separate market from thermal. Ex. 47, Wong Rep. ¶¶ 276, 283–89.

2. Plaintiffs Cannot Dodge Their Relevant Market Requirement By Claiming That The Transaction Eliminates Head-to-Head Competition

Unable to prove the alleged relevant market, Plaintiffs alternatively argue they are likely to succeed on the merits under step one of the *Baker Hughes* framework because Biocoat and Surmodics are close competitors and the transaction would "eliminate substantial head-to-head competition." Pl. Mem. 32–33. No court has ever held that Plaintiffs can carry their *prima facie* burden without defining a relevant market grounded in both the law and facts, and this Court should reject Plaintiffs' invitation to be the first.

The law is clear that a necessary predicate of a Section 7 claim is a showing that the transaction is likely to substantially reduce competition *in a relevant market. du Pont*, 353 U.S. at 593 ("Substantiality can be determined only in terms of the market affected."); *FTC v. Thomas Jefferson Univ.*, 505 F. Supp. 3d 522, 539 (E.D. Pa. 2020) (in determining if the FTC has met its burden in a Section 13(b) merger challenge, "it is first necessary to determine the relevant geographic and product markets"). There is no getting around this threshold requirement. *See also United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 84 n.35 (D.D.C. 2011) ("The Court is not aware of any modern Section 7 case in which the court dispensed with the requirement to define a relevant product market."); *RAG-Stiftung*, 436 F. Supp. 3d at 310 ("The Court is unaware of a single case in which a court has enjoined a merger, even at this preliminary stage, where the Government failed to show undue concentration in a relevant market as its *prima facie* case requires.").

Plaintiffs do not cite a single case that supports their suggestion that they can avoid proving their alleged relevant market. To the contrary, in the few cases that Plaintiffs do cite, the courts uniformly found a relevant market as a matter of law before addressing the elimination of head-to-head competition. Pl. Mem. 32–33; *see FTC v. IQVIA Holdings Inc.*, 710 F. Supp. 3d 329, 382

(S.D.N.Y. 2024) (finding the FTC had established its prima facie case by defining a relevant market and showing increased concentration through market shares and an HHI calculation); Kroger, 2024 WL 5053016, at *17 ("[P]laintiffs have already met their prima facie burden based on the post-merger changes in market concentration. A showing of elimination of head-to-head competition bolsters their case with additional evidence of loss of substantial competition between defendants."); ProMedica Health Sys., Inc. v. FTC, 749 F.3d 559, 568 (6th Cir. 2014) (affirming definition of relevant markets); see id. at 572 ("any argument about substitutes must begin with a definition of the relevant market"). Indeed, the courts in Tapestry and Sysco evaluated the elimination of head-to-head competition at step three of the burden-shifting framework, as part of their analysis as to whether the transactions would have anticompetitive harm after defining the relevant market. FTC v. Tapestry, 755 F. Supp. 3d 386, 485–86 (S.D.N.Y. 2024) (evaluating "additional evidence of anticompetitive effects" at "Step 3"); Sysco, 113 F. Supp. 3d at 61 (evaluating additional evidence of competitive harm after FTC established its *prima facie* case). Plaintiffs' citation to the FTC's own aspirational statements in its Merger Guidelines (Pl. Mem. 2)—which are in direct conflict with Supreme Court precedent—do not change the law.

3. The Divestiture Moots Plaintiffs' Concerns And Means Plaintiffs Cannot Establish Their *Prima Facie* Case

Plaintiffs' attack on a hypothetical world in which the Divestiture does not exist is beset by factual, economic and legal problems. But more importantly, the market shares Plaintiffs rely on to trigger the presumption of anticompetitive effects (based on market shares and market concentration) cannot carry their burden under step one of the *Baker Hughes* analysis because the shares do not account for the *actual* competitive dynamics that will exist when the deal closes and the Divestiture is complete. Plaintiffs thus cannot establish their *prima facie* case, and the Court should deny the preliminary injunction because Plaintiffs cannot carry their burden under step one.

See Arch Coal, 329 F. Supp. 2d at 114-15 (denying preliminary injunction when FTC challenged a transaction "that do[es] not reduce the number of competitors").

B. Plaintiffs' Market Shares Inaccurately Predict The Modified Transaction's Probable Effect On Competition

Assuming for the sake of argument that Plaintiffs could establish a *prima facie* case that the Modified Transaction (*i.e.*, with the Divestiture) is presumptively anticompetitive, Defendants can rebut that case by demonstrating that Plaintiffs' *prima facie* case and "statistics on market share, market concentration, and market concentration trends portray inaccurately the merger's probable effects on competition." *Baker Hughes*, 908 F.2d at 991 (cleaned up, discussing step two). The quantum of evidence Defendants must produce to shift the burden back to Plaintiffs is low where, as here, Plaintiffs' *prima facie* case is weak. *Arch Coal*, 329 F. Supp. 2d at 129 ("Certainly less of a showing is required from defendants to rebut a less-than-compelling *prima facie* case."). As detailed below, Plaintiffs' one-sided summary of the evidence does not accurately predict the effects of the transaction, and they cannot show an anticompetitive effect on "future competition." *Baker Hughes*, 908 F.2d at 991.⁶⁴

1. Plaintiffs' Market Shares Overstate The Modified Transaction's Likely Competitive Effects Because They Do Not Reflect Current Competition

Plaintiffs' assertion that revenue shares are indicative of future harm ignores the role long-term contracts play in this industry. Plaintiffs' selective citation to the FTC's Merger Guidelines to support their claim that revenue from past competitive wins is "predictive of competitive significance into the future" (Pl. Mem. 30 n.2) proves this point. Plaintiffs ignore the Guidelines'

⁶⁴ If the Court evaluates the Divestiture as part of Defendants' rebuttal in the burden-shifting framework, for the reasons explained above, the Plaintiffs' market shares inaccurately predict the transaction's effect on competition, even accepting Plaintiffs' incorrect market definition. Plaintiffs cannot produce additional evidence of anticompetitive effects to meet their ultimate burden of persuasion.

caveat that past market shares should be "informative about the market realities of competition in the particular market and firms' future competitive significance." The Supreme Court addressed precisely this issue when it analyzed the relevance of long-term contracts in the coal industry in *General Dynamics*, 415 U.S. 486 (1974). It noted that, unlike sales of "groceries or beer ... [where] statistics involving annual sales naturally indicate the power of each company to compete in the future," because coal "is delivered under long-term requirements contracts ... such sales thus do not represent the exercise of competitive power but rather the obligation to fulfill previously negotiated contracts at a previously fixed price." *Id.* at 501.

So too here. Revenue-based market shares reflect the performance of medical devices that

blockbuster device. Current sales cannot be used to predict current or future shares with the requisite certainty, as *General Dynamics* recognizes.

As Dr. Wong explains, the superior methodology for calculating market share in this case is based on the FDA's publicly available data on all U.S. medical devices that have been approved. Ex. 47, Wong Rep. ¶¶ 34, 312, 328-331. Dr. Wong's calculations show—even in Plaintiffs' outsourced hydrophilic coatings market and ignoring the Divestiture—Biocoat's and Surmodics's properly calculated market shares are no more than and and respectively, and combined. *Id.* ¶¶ 35, 305–06, 333, Exhibit 15. These shares would result in a post-transaction HHI of no more than and likely much lower—well below the presumptive thresholds outlined in the FTC's own guidelines for raising competitive concerns. *Id.* ¶¶ 35, 305–06, 334, Exhibit 15.

2. Plaintiffs' Remaining Arguments Regarding Entry Are Legally And Factually Unsupported

While the Divesture moots the need to evaluate them, a few of Plaintiffs' step two arguments regarding entry require a brief response to correct the law and the facts. The record is clear that rapid entry and expansion is not only possible, it occurs often. While entry is not frictionless, many companies and investors could enter quickly and effectively. *Id.* ¶¶ 299–02. And existing international suppliers could readily expand to serve the US. *Id.* ¶¶ 297–98.

VitaTek's recent launch of a new hydrophilic coating (Ex. 48, BusinessWire, "VitaCoat Open-

Source Hydrophilic Coatings Now Available on Chamfr," January 14, 2025, www.businesswire.com/news/home/20250114363373/en/VitaCoat-Open-Source-Hydrophilic-Coatings-Now-Available-on-Chamfr); and Noanix's introduction of hydrophilic coatings (Ex. 50, Noanix, "History," noanix.com/about-us/history/).

3. The Divestiture Eliminates The Competitive Concern And Moots Any Argument That Past Shares Are Indicative Of Future Harm

In the real world where the Divestiture occurs at closing, Defendants also carry their burden under step two because Plaintiffs' market shares bear no resemblance to future competition. The question is whether past success "impl[ies] an ability to continue to dominate with at least equal vigor." *General Dynamics*, 415 U.S. at 501. Here, the Plaintiffs' market shares and concentration estimates (which do not incorporate the Divestiture) fail to predict the transactions' probable effect on competition because they do not account for the fact that the Divestiture removes any concerns the transaction could raise under Section 7. Indeed, Dr. Wong concludes that given the comprehensive nature of the Divestiture, the transactions are *deconcentrating*, meaning when the deal closes, the market will be less concentrated relative to the status quo. Ex. 47, Wong Rep. ¶¶ 306–10, 350.

Plaintiffs' suggestion that Defendants' Divestiture must eliminate any risk of harm and fully recreate lost competition (Pl. Mem. 52) is beside the point because there is no serious argument that the Divestiture is deficient in any way. Regardless, Plaintiffs are wrong as a matter of law. The Divestiture does not have to "preserve exactly the same level of competition that existed before the merger." *United States v. UnitedHealth Grp. Inc.*, 630 F. Supp. 3d 118, 133 (D.D.C. 2022); *Illumina, Inc. v. FTC*, 88 F.4th 1036, 1059 (5th Cir. 2023) (the court need only find that the proposed fix "sufficiently *mitigated* the merger's effect such that it was no longer

likely to *substantially* lessen competition"). Holding otherwise would "effectively erase the word 'substantially' from Section 7." *UnitedHealth*, 630 F. Supp. 3d at 132-33. That is not the law.⁶⁵

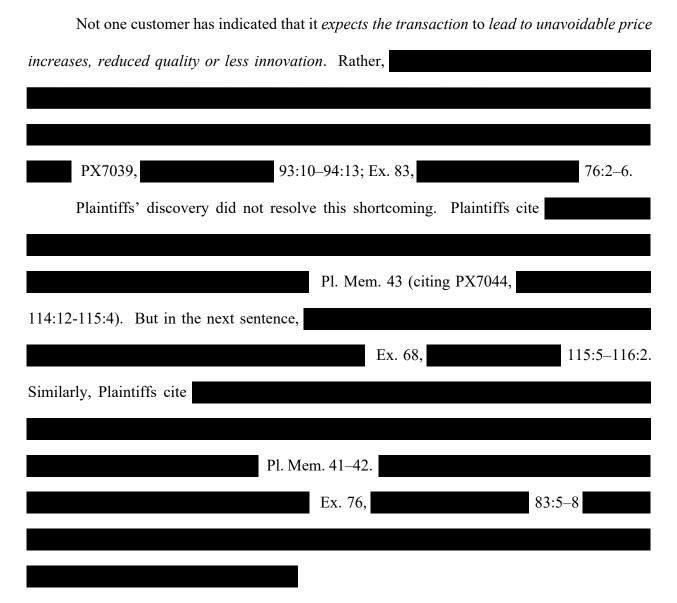
C. The Record Confirms That The Transaction Will Not Have Substantial Anticompetitive Effects

Under step three, Plaintiffs must prove that they are likely to prevail on the merits of their claim that the Modified Transaction is likely to have substantial anticompetitive effects in the alleged relevant market. The elimination of some head-to-head competition and "some lessening of competition" is not sufficient under the law. *See Int'l Shoe Co. v. FTC*, 280 U.S. 291, 298 (1930) (noting that Section 7 "deals only with such acquisitions as probably will result in lessening competition to a substantial degree"). To underscore just how competitive the coatings industry is, Plaintiffs cannot prove substantial anticompetitive effects. That is the case in Plaintiffs' hypothetical world without the Divestiture or inclusive of it.

1. The Record Lacks The Evidence Courts Normally Cite As Proof Of Anticompetitive Effects

Plaintiffs recognize that they have the burden to connect the alleged loss of competition to an anticompetitive effect, whether in the form of reduced quality or innovation, or higher prices. Pl. Mem. 2. But Plaintiffs work stops there. They have not shown that the Merged Firm will adversely affect customers, that customers *will* pay higher prices, or that the Merged Firm or its competitors *will* reduce quality or innovation.

⁶⁵ Plaintiffs rely on *Kroger* to state that Defendants must show the divestiture would fully offset any competitive harm. Pl. Mem. 52. *Kroger* itself quoted *Illumina* for the proposition that the "divestiture is successful rebuttal evidence if it 'sufficiently mitigate[s] the merger's effect such that it [is] no longer likely to substantially lessen competition." *FTC v. Kroger Co.*, 2024 WL 5053016, at *24 (D. Or. Dec. 10, 2024) (quoting *Illumina*, 88 F.4th at 1059). Regardless, *Kroger* is inapt as, after considering the divested assets, the FTC showed that hundreds of markets were still presumptively unlawful based on market shares and increased concentration and "would create a significantly smaller firm than either defendant pre-merger." *Id.* at *25–26.



For context, Plaintiffs lack the evidence that courts cite in Section 7 cases as sufficient proof of likely anticompetitive effects. Unlike *H&R Block*, 833 F. Supp. 2d at 82, the documents do not show that Biocoat is worried that Surmodics is "put[ting] downward pressure on [Biocoat's] pricing ability." Similarly, unlike in *FTC v. Whole Foods Mkt.*, there is no hint that the purpose of the deal is to eliminate competition. 548 F.3d 1028, 1049 (D.D.C. 2009) (Tatel, J., concurring) (Whole Foods CEO told Board target company is only company that could "be a meaningful springboard for another player to get into this space," and "[e]liminating them means eliminating

this threat forever, or almost forever"). There is no admission that the merger "ha[d] the greatest potential for higher [] rates" and could "[h]arm the community by forcing higher [] rates on them." *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 563 (6th Cir. 2014). This type of admission was also seen in *IQVIA*, a case Plaintiffs heavily rely on, where the acquirer called itself "by far the largest data provider in this vertical" prior to the proposed acquisition, and both merging parties had voluminous normal course documents reflecting direct competition on price, with both companies dropping prices in response to the other's rates. *IQVIA*, 710 F. Supp. 3d at 345, 384. And unlike in *Tronox*, Plaintiffs have not shown that either side leveraged a consolidated market to "slow down production" to eliminate inventory so "prices will rise." *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 208 (D.D.C. 2018).

2. Plaintiffs Offer No Examples Of Price Competition That Benefitted Customers

Lacking proof that the transaction will have anticompetitive effects, Plaintiffs over-index on Biocoat and Surmodics passing initial testing for a handful of device opportunities, which is not disputed. What matters under Section 7, however, is whether the loss of head-to-head competition will result in higher prices, reduced quality, or reduced innovation. Here, Plaintiffs have not shown that Biocoat and Surmodics regularly compete on the pricing of their coatings. Of customers with commercial medical devices, only out of customers purchased from both Biocoat and Surmodics in the last years. Ex. 47, Wong Rep. ¶ 17, 100, Exhibit 3A. Those common customers comprise only of the combined customer base for the two firms. Id. ¶ 17, 102, Exhibit 3B. The data shows that Biocoat customers more frequently turn to —than Surmodics. Id. ¶ 17, 104, Exhibit 3I. More broadly, Dr. Wong estimates

that customers industry-wide tested both Biocoat and Surmodics coatings on their devices *less* than of the time. Id. ¶¶ 17, 141, Exhibit 8I.

Defendants' documents shows the same: customers have choices beyond Biocoat and Surmodics. For example, when Biocoat renewed an agreement with the customer threatened to move to in-house coatings and used that threat to attempt to reduce royalty rates on its new contract. Ex. 6 at -816 (discussing ... When ... When ... When ... When ... When ... When ... Ex. 28 at -562-565. ... also constrains Surmodics's price. ... tested a product with Surmodics but selected ... because ... Ex. 73, ... 82:6-15; Ex. 18 at -710 ... Surmodics' documents also show competition on price and quality with competitors

D. Dr. Fix's "Merger Simulation" Is Incurably Flawed

Plaintiffs do not rely on Dr. Fix to address competitive effects in their pre-hearing brief. Nor could they because Dr. Fix's so-called "merger simulation" is inherently flawed and implausibly predicts that prices will increase by for Biocoat and for Surmodics. Ex. 47, Wong Rep. ¶¶ 88, 190 (citing Fix Rep. ¶¶ 186, 187). For completeness we address it briefly here.

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⁶⁶ See Ex. 38 at -580

First, Dr. Fix's merger simulation is flawed because it simulates a world that does not exist by leaving out the Divestiture. *Id.* ¶ 191. Second, it is based on Dr. Fix's flawed market share estimates discussed above. Id. ¶ 192. Once those share estimates are replaced with estimates derived from FDA opportunity data, the estimated price effect drops to near zero. Id.; see RAG-Stiftung, 436 F. Supp. 3d at 319 (finding merger simulation model "of little use" because the model's "inputs" of market shares were flawed). Third, the design is flawed; it is well-documented in economic literature that "upward pricing pressure" models like the one Dr. Fix uses will always estimate a post-transaction price increase. Ex. 47, Wong Rep. ¶ 193. For example, Dr. Fix's merger simulation predicts that a merger of Surmodics with a very small competitor would result in price increases of *Id.* ¶¶ 193-94, Exhibit 14B. Finally, there is no real-world way to implement the implausibly high average price increase Dr. Fix's model predicts. Companies in this industry see few new opportunities each year. To earn an incremental in revenue in a single year, Biocoat would have to raise price more than on competitive opportunities. *Id*. ¶ 195.

Instead of simulating competition, Dr. Wong studied actual industry events to analyze whether the transaction could have a competitive effect. As Dr. Wong shows, when Biocoat introduced a UV coating in February 2020, it had no measurable effect on Surmodics' sales. *Id.* ¶¶ 215-19, Exhibits 13A-C. And when Surmodics introduced a new formulation--Preside--the introduction had no effect on Biocoat's sales. *Id.* ¶¶ 220-22, Exhibits 13D-F. While Dr. Fix assumes head-to-head competition will be eliminated by the transaction, Dr. Wong's analysis confirms that it hardly existed in the first place.

As in *RAG-Stiftung*, "unlike many cases in which the FTC alleges that a proposed merger would be anticompetitive, the record contains no evidence that [acquirer] intends to raise prices

post-merger." 436 F. Supp. 3d at 320. Under the proper "totality-of-the-circumstances approach" and "weighing a variety of factors to determine the effects" of the transaction on competition, Plaintiffs cannot show any likely substantial lessening of competition. *Baker Hughes Inc.*, 908 F.2d at 984.

E. The Divestiture Eliminates Any Possibility of Anticompetitive Effects

Defendants' Divestiture fully addresses Plaintiffs' concerns: not only is the deal not anticompetitive, but with as a buyer the Divestiture introduces a new, robust competitor in both thermal and UV coatings. is committed to competing aggressively in hydrophilic coatings. Ex. 34 at -746. Indeed, is a far more formidable competitor than either of Biocoat or Surmodics today. As testified,

Ex. 61, 331:23-333:16.

The absence of any possibility of anticompetitive effects post-Divestiture means Plaintiffs cannot carry their burden. *See Arch Coal*, 329 F. Supp. 2d at 124, 130 (finding that after merger and divestiture the FTC did not show likely anticompetitive effects); *RAG-Stiftung*, 436 F. Supp. 3d at 304 (defendants met burden to show that the buyer of divested assets "will replace [defendant's] competitive intensity"); *UnitedHealth*, 630 F. Supp. 3d at 135 ("the trial evidence and the record demonstrated that the divestiture will preserve competition in the market").

III. PLAINTIFFS CANNOT SHOW A BALANCE OF EQUITIES WEIGHS IN THEIR FAVOR

To determine whether to grant a preliminary injunction under Section 13(b), a court must balance the equities. *FTC v. Weyerhaeuser Co.*, 665 F.2d 1072, 1082-83 (D.C. Cir. 1981). Plaintiffs must "prove that the harm to the parties and to the public that would flow from a preliminary injunction is outweighed by the harm to competition, if any, that would occur in the

period between denial of a preliminary injunction and the final adjudication of the merits of the Section 7 claim." *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 86 (N.D. Ill. 1981); *see also Thomas Jefferson Univ.*, 505 F. Supp. 3d at 538. Plaintiffs cannot prove the equities weigh in their favor when they continue to litigate a fact pattern that does not exist.

CONCLUSION

Defendants respectfully request the Court deny Plaintiffs' preliminary injunction motion.

Date: August 3, 2025 Respectfully submitted,

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⁶⁷ See FTC v. Elders Grain, Inc., 868 F.2d 901, 905 (7th Cir. 1989) (noting "the cynical though perhaps realistic speculation that since the Commission is both the instigator and the trier of the cases filed before it, the decision to seek a preliminary injunction is a good predictor of the likely outcome of the administrative proceeding").

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